

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



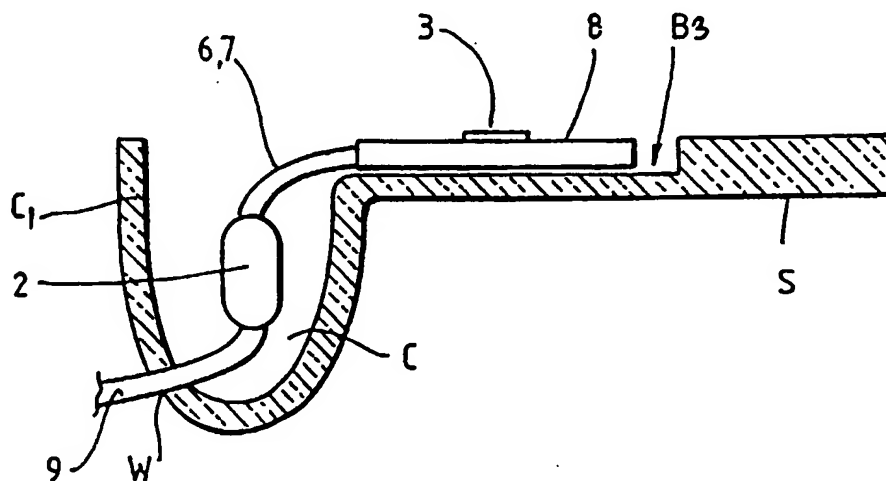
(43) International Publication Date
15 February 2001 (15.02.2001)

PCT

(10) International Publication Number
WO 01/10369 A1

- (51) International Patent Classification⁷: A61F 11/04, 2/18 (74) Agent: FREEHILLS CARTER SMITH BEADLE; 101 Collins Street, Melbourne, VIC 3000 (AU).
- (21) International Application Number: PCT/AU00/00936
- (22) International Filing Date: 7 August 2000 (07.08.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PQ 2071 6 August 1999 (06.08.1999) AU
- (71) Applicant (for all designated States except US): THE UNIVERSITY OF MELBOURNE [AU/AU]; Grattan Street, Parkville, VIC 3052 (AU).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): CLARK, Graeme, Melbourne [AU/AU]; 13 Banoon Road, Eltham, VIC 3095 (AU). PYMAN, Brian, Clive [AU/AU]; 53 Victoria Crescent, Mont Albert, VIC 3127 (AU). O'LEARY, Stephen, John [AU/AU]; 1104 Whitehorse Road, Box Hill, VIC 3128 (AU).
- Published:
— With international search report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVED COCHLEAR IMPLANT PACKAGE



(57) Abstract: An implant package for a cochlear implant, including stimulator electronics contained within a protective housing (2) and being coupled to an electrode array (9) for insertion into the cochlea of a patient, and being further coupled to a receiving and/or transmitting coil (8) enclosed within a protective casing, said protective housing being dimensioned and shaped to be capable of location within the mastoid cavity (C) of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing (2) and the protective casing (8).

WO 01/10369 A1

BEST AVAILABLE COPY

IMPROVED COCHLEAR IMPLANT PACKAGE

Field of the Invention

This invention relates to improvements in cochlear implants, and more particularly to improvements relating to the shapes of implant packages, e.g. receiver-stimulator packages, to enable the cochlear implant to be positioned in a patient in a more desirable location than the location presently used.

Background of the Invention

Present cochlear implant receiver-stimulators are placed in a patient by drilling a bed into and through the posterior section of the mastoid bone lying behind the ear. The bed is usually made by drilling the bone down to the lining of the brain or dura mater. The receiver-stimulator of the Nucleus cochlear implant made by Cochlear Limited has a receiver-stimulator package made from titanium which houses the stimulation electronics and which is fitted into the bed in the mastoid bone. A receiver coil extends from the back end of the package and lies superficial to the bone. Other cochlear implants have included packages made from ceramic material and these are usually placed completely within a bed drilled down to the lining of the brain, especially in young children.

In young children, placing either of the above packages in the mastoid bone some distance behind the ear can lead to the packages creating an external swelling, which can be unsightly. More importantly, such placements of the package can lead to serious damage caused by excessive impact to the head in the area adjacent the implant. Such impact can lead to fractures of the electrode where it exits the package, or cracking or damage of the package itself. In addition, because the packages are placed in this particular location, especially where a bed is drilled down to the lining of the brain, it is possible for excessive impact to cause the package to enter the cranial cavity and damage structures including the brain.

- 2 -

Summary of the Invention and Object

It is an object of the present invention to provide an improved implant package for a cochlear implant shaped to be received in a more desirable location within the skull of the patient.

5 The invention provides an implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective
10 housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.

By positioning the implant electronics housing in this way, the housing is
15 less exposed to the risk of trauma caused by excessive blows to the head as it lies below the surface of the skull bone and is therefore less susceptible to a direct blow, and is additionally protected by the overlying pinna. The flexible coupling enables the coil to be placed in an optimal position and, depending on the anatomy and the age of the person, over time the coupling would adjust to
20 any changes in head shape.

Advantageously, the implant package is electrically coupled to the electrode array and is further electrically coupled to the receiving and/or transmitting coil.

In a preferred form, the flexible coupling is made from a material having
25 memory so that the coupling retains its desired shape when installed in the mastoid cavity. The flexible connection can include one or more flexible arms which contain the electrical leads for connecting the implant electronics in the protective housing to the transmitter/receiver coil. While two arms are shown in the preferred embodiment, one arm may have the advantage of reducing the
30 inductive effects between the leads within the arms and the magnetic coil of the transmitter/receiver.

- 3 -

The implant package is preferably a receiver-stimulator package for a cochlear implant.

Brief Description of the Invention

5 A preferred embodiment of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 schematically illustrates one embodiment, and

Figure 2 is a schematic cross section illustrating the positioning of the protective casing and the protective housing relative to the ear canal, the
10 mastoid cavity and the drilled bed in the skull.

Description of the Preferred Embodiment

Anatomical dissections show that there is a gutter lying between the sigmoid sinus, posterior osseous ear canal, the mastoid tip and the floor of
15 middle fossa where an appropriately shaped housing for the implant unit can be placed so that the housing is not exposed above the surface of the bone.

As illustrated in the drawings, the housing 2 comprises a narrow elongate rectangular housing having rounded ends, somewhat like a flattened ovoid or lozenge shape, which is received in the mastoid cavity C referred to above
20 adjacent the ear canal C₁. The housing 2 may be made from titanium, similar to the Nucleus device, or from cast or moulded ceramic material.

As described above, the protective housing 2 for the implant electronics, in this case the receiver-stimulator electronics, is connected by suitable leads 4, 5 to a transmitter/receiver coil 3, the leads 4, 5 being contained within flexible
25 arms 6, 7 of inert material such as silicone rubber. If desired, the arms 6, 7 can be formed from or incorporate a material having memory so that the arms retain their manufactured shape after installation.

The coil 3 is enclosed within a protective casing 8, which is received in a drilled bed B₃ in the mastoid bone behind the ear. Suitably shaped beds B₁, B₂
30 connecting the mastoid cavity and the drilled bed B₃ with the skull S receive the flexible arms 6, 7 containing the connecting leads 4, 5. A further lead 9 extends

from the housing 2 into the ear canal C_1 through a window W and terminates in an electrode array (not shown) which is implanted in the cochlea.

Since the receiver-stimulator housing 2 is located in the mastoid cavity C, below the surface of the bone, it is less susceptible to damage and is
5 protected and hidden by the overlying pinna. The flexible arm(s) 6, 7 allow optional positioning of the coil and permit changes in head shape.

The receiver-stimulator electronics, the transmitter/receiver coil, and the electrode array for implantation in the cochlea of the patient are configured in
10 accordance with the patent literature relating to the cochlear implant technology and do not form any part of the present invention.

While one preferred shape for the protective housing has been described above, it will be appreciated that different shapes, which are capable of lying wholly within the gutter forming part of the mastoid cavity, can be adopted without departing from the essence of the invention defined above.

15 It is also envisaged that whilst the above embodiment is described with reference to a conventional cochlear implant system, i.e. one with a receiver-stimulator that receives coded signals from an external unit and provides stimulation to the cochlea accordingly, the present invention could equally be applied to a totally implanted cochlear implant system. In such a system the
20 implant unit has the capability of functioning without the need for any external devices, at least for a defined period of time.

- 5 -

CLAIMS:

1. An implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.
2. The implant package of claim 1, wherein the flexible connection facilitates optimal positioning of the coil, depending on the anatomy and age of the patient.
3. The implant package of claim 1 or 2, wherein the flexibility of the flexible connection between the protective housing and the protective casing is such as to allow changes in head shape as the patient grows.
4. The implant package of any preceding claim, wherein the flexible connection is made from a material having memory so that the coupling retains its shape after installation into the mastoid cavity.
5. The implant package of any preceding claim, wherein the implant package is electrically coupled to the electrode array.
6. The implant package of any preceding claim, wherein the implant package is electrically coupled to the receiving and/or transmitting coil.
7. The implant package of claim 6, wherein the flexible connection includes one or more flexible arms containing leads which electrically connect the implant electronics to the receiving and/or transmitting coil.
8. The implant package of any preceding claim, wherein the implant package is a receiver-stimulator package for a cochlear implant.

1/1

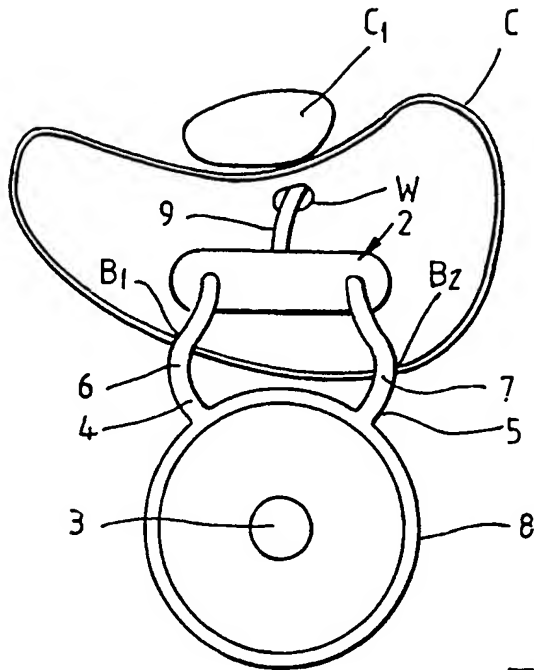


FIG. 1.

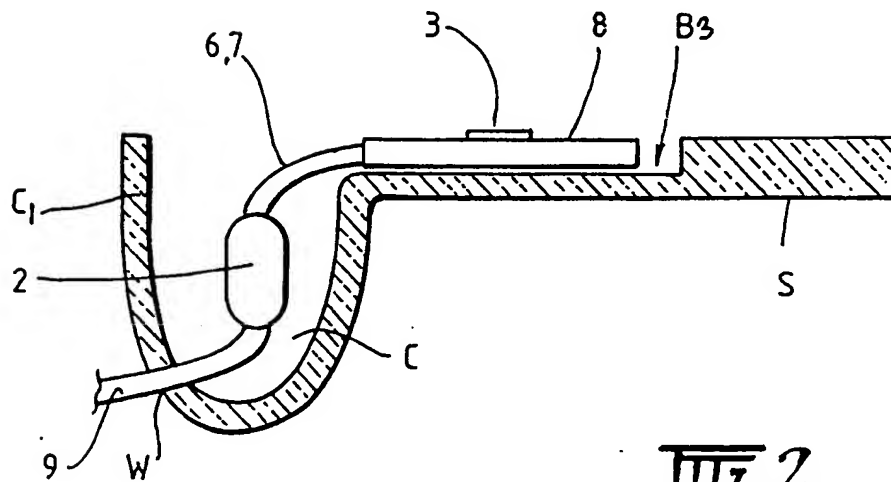


FIG. 2.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00936

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61F 11/04, 2/18		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61F 2/1C, 11/1C		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC AS ABOVE		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT JAPIO		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/06108 A (ALFRED E MANN FOUNDATION FOR SCIENTIFIC RESEARCH et al) 11 February 1999 See page 3 lines 1-9, page 5 line 28-page 6 line 9 and page 20 lines 1-16.	1-3, 5-8
A	US 5814095 A (MULLER et al) 29 September 1998 See figures 1-4.	
A	US 5558618 A (MANIGLIA) 24 September 1996 See entire document.	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 September 2000		Date of mailing of the international search report 10 OCT 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer JOHN HO Telephone No : (02) 6283 2329

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00936

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97/05673 A (COCHLEAR PTY LTD) 13 February 1997 See entire document.	
A	WO 83/00999 A (HOCHMAIR) 31 March 1983 See entire document.	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00936

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9906108	AU	86804/98	EP	999874		
US	5814095	—	DE	19638158	EP	831673	DE
		19638159	EP	831674			
US	5558618	US	5906635				
WO	9705673	AU	31054/95				
WO	8300999	AU	88333/82	AU	89540/82	BE	894422
		BR	8207864	CA	1194552	DK	1993/83
		EP	76069	US	4419995		
END OF ANNEX							

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.